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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STOCK JR, GORDON J

ART UNIT PAPER NUMBER

2877

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/14.

Office Action Summary**Application No.**

09/821,571

Applicant(s)

MCCAFFREY ET AL.

Examiner

Gordon J Stock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39-42 and 44-56 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 12, 15-22, 30-33, 37, 38, 43 and 57-61 is/are rejected.
- 7) ☒ Claim(s) 6, 9-11, 13, 14, 23-29, 34-36 and 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. Drawing corrections for Fig. 5 that were received on December 8, 2003 are accepted by the Examiner.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "38" and "40" has been used to designate both Door/LED and CPU of Fig. 2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Examiner suggests an arrow going from 38 with designation "TO 34" and an arrow going to 34 with designation "FROM 38;" an arrow going from 40 with designation "TO 34" and an arrow going to 34 with designation "FROM 40."
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 122 and 124 from page 18 paragraph 73. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1, 7, 12, 43, 57, and 61** are rejected under 35 U.S.C. 102(e) as being anticipated by **Silver et al. (6,372,511)**.

As for **claim 1**, Silver in a swabbing means and method in chemiluminescence discloses a housing for enclosing the sample in the absence of light; a first light sensor inside the housing; a second light sensor shielded from the luminescence by a LCD shutter and a controller that processes the signals (Figs. 1, 5a, 15; col. 21, lines 35-57; col. 22, lines 10-67).

As for **claim 7**, see **claim 1** above. In addition, Silver discloses a pair of analog to digital converters digitizing the sample and reference signals. The signals are conditioned (Fig. 15; col. 21, lines 35-57; col. 22, lines 10-67). And determination of dark noise suggests subtraction of signals (col. 23, lines 5-47).

As for **claim 12**, see **claim 1** above. In addition, Silver discloses window in the sample compartment and a door, a hinged area, and a consumable (col. 7, lines 50-67; col. 8, lines 1-45; Fig. 5a).

As for **claims 43, 57, 61**, Silver discloses a housing provided with a sample compartment; a consumable collecting the sample and removably inserted into the sample compartment; a detection assembly located in the housing; a controller having multiple modes of operation; providing a first photodiode, a second photodiode, and a controller; comparing signals with a threshold; displaying the resulting signal indicative of the sample; detecting a consumable containing the sample in the sample compartment with a transparent bottom comprising a window (Figs. 1, 5a, 15; 9a-9c; col. 7, lines 50-67; col. 8, lines 1-45; col. 9, lines 1-20; col. 20, lines 5-25; col. 22, lines 5-67).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 2-3, 22, 33, 38, 59, and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Taylor et al. (6,187,267)** and **Bryan (6,458,547)** and **Anderson et al. (4,818,883)**.

As for **claims 2-3, and 22**, see **claim 1** above. And for **claims 33 and 38**, refer to **claim 57** above. In addition, Silver discloses integrators (Fig. 15) and that processing may be done serially or in parallel (col. 21, lines 35-55). As for switching, temperature, and capacitors, Silver is silent. However, Bryan in a detection device teaches that capacitors with cycle intervals and comparisons between a measurement signal and a reference signal is used in determining concentrations of an analyte and that switched capacitive circuits are used for measuring concentrations (col. 41, lines 55-67; col. 42, lines 1-65). In addition, Taylor in a chemiluminescence device teaches the use of current integration mode in light detection using integration capacitors (col. 39, lines 25-50). And Ghaed in a luminometer apparatus teaches that dark current may drift due to temperature (col. 1, lines 20-25). Therefore, it would be obvious to one skilled in the art that switched integrators with capacitors were present for switched integrators with capacitors are used in detecting light and determining concentrations of analyte in chemiluminescent devices. In addition, it would be obvious that a reference signal indicating temperature was present, for Silver's system took dark current readings which drift due to temperature.

As for **claims 59-60**, Silver discloses generating a sample signal; generating a reference signal; integrating signals; digitizing signals; the suggests subtracting signals for calibrating may be done as well as dark current being found; integration periods, temporal intervals are used. (Fig. 15; col. 21, lines 35-57; col. 22, lines 10-67)). In addition, Bryan in a detection device teaches that capacitors with cycle intervals and comparisons between a measurement signal and a reference signal is used in determining concentrations of an analyte and that switched capacitive circuits are used for measuring concentrations (col. 41, lines 55-67; col. 42, lines 1-65). In addition, Taylor in a chemiluminescence device teaches the use of current integration mode in light detection using integration capacitors (col. 39, lines 25-50). Therefore, it would be obvious to one skilled in the art that switched integrators with capacitors were present for switched integrators with capacitors are used in detecting light and determining concentrations of analyte in chemiluminescent devices. As for responsive to temperature, he is silent. Ghaed in a luminometer apparatus teaches that dark current may drift due to temperature (col. 1, lines 20-25). In addition, it would be obvious that a reference signal indicating temperature was present, for Silver's system took dark current readings which drift due to temperature.

8. **Claims 4-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Taylor et al. (6,187,267)** and **Bryan (6,458,547)**.

As for **claims 4-5 and 22**, see **claims 1-2** above. In addition, he discloses integrators and temporal intervals for particular predetermined amounts to be detected (Fig. 15; col. 21, lines 35-57; col. 22, lines 10-67)). As for solid state switching in capacitive circuits with particular time periods for detection, Silver's system implies it by the integration and the intervals being performed. However, Bryan in a detection device teaches that capacitors with cycle intervals

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and comparisons between a measurement signal and a reference signal is used in determining concentrations of an analyte and that switched capacitive circuits are used for measuring concentrations with time intervals for switching (col. 41, lines 55-67; col. 42, lines 1-65). In addition, Taylor in a chemiluminescence device teaches the use of current integration mode in light detection using integration capacitors (col. 39, lines 25-50). Therefore, it would be obvious to one skilled in the art that switched integrators with capacitors were present with defined intervals for opening and closing switches for switched integrators with capacitors are used in detecting light and determining concentrations of analyte in chemiluminescent devices by using intervals of closing and opening switches.

9. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wood (5,650,289)**.

As for **claim 8**, see **claim 1** above. As for calculating logarithmic number and displaying the log, Silver is silent. However, Wood in luciferase assay compositions teaches that there is a logarithmic relationship between luciferase concentration and light (Fig. 6). Therefore, it would be obvious to one skilled in the art to have a logarithm calculated and displayed for luciferase concentration has a logarithmic relationship with light.

10. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wright et al. (6,660,469)**.

As for **claim 15**, see **claim 1**. As for three levels of intensity, Silver is silent. However, Wright in a luminometer system teaches having three levels of concentration range (Fig. 1: 61-63; col. 7, lines 55-65; col. 8, lines 1-10). Therefore, it would be obvious to one skilled in the art

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to have the system comprise three levels of intensity low, mid, high in order to display low, normal, and or abnormal levels of an analyte being tested.

11. **Claims 16-21** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wright et al. (6,660,469)** further in view of **Ghaed et al. (5,700,427)**.

As for **claims 16-21**, see **claim 15** above. They are silent concerning an LED being turned on and off at predetermined times for comparison to predetermined levels of intensity: low, mid, and high. However, Ghaed in an apparatus for luminescent measurements teaches including an LED for testing the detector's performance (Fig. 25; col. 26, lines 1-20). Therefore, it would be obvious to one skilled in the art at the time the invention was made to have a reference LED in order to test performance of the photodetectors. Thereby, it would be obvious to one skilled to have the LED have three different levels of illumination to test the photodetector at the three levels of detection range: low, mid, and high.

12. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Liljestrand et al. (6,200,531)**.

As for **claim 31**, see **claim 30**. Silver is silent concerning a conductive chassis. However, Liljestrand in an apparatus for luminescent measurements teaches having a conductive chassis in order to protect the system from external environmental variations (col. 24, lines 8-20). Therefore, it would be obvious to one skilled in the art at the time the invention was made to have the chassis be conductive in order to shield the system from external environmental variations.

13. **Claims 30, 32, 37, and 58** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)**.

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As for **claims 30, 32, 37 and 58**, Silver discloses the following: a housing provided with a sample compartment; a detection assembly inside the housing; a transparent window, a LCD shutter, a controller inside the housing for determining whether a resulting signal processed is indicative of the sample; a consumable removably inserted in the sample compartment; a predetermined threshold; a display device (Figs. 1, 5a, 15; 9a-9c; col. 7, lines 50-67; col. 8, lines 1-45; col. 9, lines 1-20; col. 20, lines 5-25; col. 22, lines 5-67).

As for a conductive film on the LCD shutter comprising indium tin oxide or a plastic, Silver is silent. However, Examiner takes official notice that it is well known in the art that liquid crystals comprise indium tin oxide and liquid crystal devices comprise conductive plastic layers. Therefore, it would be obvious to one skilled in the art that the LCD shutter comprises indium tin oxide and/or conductive plastic, for liquid crystals may comprise indium tin oxide and liquid crystal devices comprise conductive plastic layers.

Response to Arguments

14. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

15. **Claims 39-42 and 44-56** are allowed.

16. **Claims 6, 9-11, 13, 14, 23-29, 34-36 and 62** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As to **claim 6**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a hand held device the particular software, in combination with the rest of the limitations of **claim 6**.

As to **claim 9**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device “a calibration mode, wherein the cleanliness of the window is controlled” in combination with the rest of the limitations of **claim 9-11; 23-27**.

As to **claim 13**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, “a LED pressed into a peripheral wall of the sample compartment” in combination with the rest of the limitations of **claim 13**.

As to **claim 14**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, “preventing the device from operating in response to a signal indicative of an open door” in combination with the rest of the limitations of **claim 14**.

As to **claim 28**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, “a pair of plano-convex lens” in combination with the rest of the limitations of **claim 28**.

As to **claim 29**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, software for determining the presence of holes in the door in combination with the rest of the limitations of **claim 29**.

As to **claim 34**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a bandpass filter” in combination with the rest of the limitations of **claim 34**.

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As to **claim 35**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a bandpass filter” in combination with the rest of the limitations of **claim 35**.

As to **claim 36**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a calibration value indicative of the cleanliness of the transparent window” in combination with the rest of the limitations of **claim 36**.

As to **claim 39**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device “the detection assembly generating a calibration signal indicating cleanliness of the transparent window” in combination with the rest of the limitations of **claims 39-42, 44-49, and 51-56**.

As to **claim 50**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld assay device the first, second, and third modes, in combination with the rest of the limitations of **claim 50**.

As to **claim 62**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a method of measuring the presence of a sample “the step of determining the cleanliness of the transparent bottom before determining the resulting signal” in combination with the rest of the limitations of **claim 62**.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

1) Contain either a statement “DRAFT” or “PROPOSED AMENDMENT” on the fax cover sheet; and

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2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

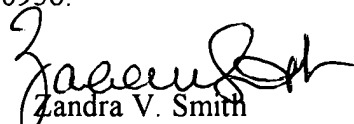
Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (703) 872-9306

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (571) 272-2431. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

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gs

March 20, 2004


Zandra V. Smith
Primary Examiner
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